Claims 8-10 stand objected to for failing to further limit the previous claim. The specific use of a composition of matter may be claimed as a *method of use*, 35 USC 101, or an *article of manufacture*, Schering Corp. v. Precision-Cosmet Co., Inc., 227 USPQ 278, 281 (D.Del. 1985). In Schering Corp., the patentee used "TBS," a known-in-the-art polymer, to make contact lenses. The patent did not claim TBS. Rather, the patent claimed contact lenses made from TBS. The Federal court ruled the contact lens -the article of manufacture- is patentably distinct from the composition of matter (TBS). The Federal court said, "the Schering patent discloses more than the mere chemical composition TBS; it claims contact lenses that have been cut and shaped from the raw compound itself. Such a modification is legally significant and prevents the challenged claims from" being anticipated by prior art disclosing TBS.

In the immediate case, claims 8-10 claim not a composition of matter, but a specific article of manufacture made from that composition of matter. Claims 8-10 are thus amended not to change their scope, but clarify that they require a label for a specific class of use.

Claims 1, 2, 4, 5, 7, 15, 16, 18 are amended to replace the term "testosterone blocker" with "5α-reductase inhibitor." The OFFICE ACTION says inhibitors of 5-reductase are testosterone blockers (not testosterone inhibitors). OFFICE ACTION at 7 (28 Sept. 2001). The OFFICE ACTION relies on SPECIFICATION page 6. That page, however, says testosterone *inhibitor*, not testosterone *blocker*. The term "testosterone blocker" has therefore been replaced throughout the claims with the term "5α-reductase inhibitor," which term is supported at the page cited by the Examiner.

III. PRIOR ART REJECTIONS

A. Partain, United States Letters Patent No. 4,946,870

Various claims stand rejected over Partain. Partain cannot anticipate, because Partain teaches away from the claimed combinations.

Partain teaches using chitosan derivatives as skin "humectants" (moisturizers) to moisturize the skin to enhance the absorption of certain pharmaceutical actives. Col. 3 line 53-60. Partain teaches combining a humectant with a combination of minoxidil and nicotinic acid. *See* Example 7. Partain says minoxidil and nicotinic acid may act synergistically. In so doing, Partain fails to teach that skin penetrant will work with minoxidil alone. Because Partain teaches

away from using minoxidil and penetration enhancer alone (without needing nicotinic acid), Partain teaches away form the claimed combinations.

B. Bazzano United States Letters Patent No. 5,183,817

1. Bazzano Fails To Anticipate any Claims

Claims 1-4 stand rejected as anticipated by Bazzano. Bazzano cannot anticipate the claims because Bazzano fails to teach *"penetration enhancer"* and teaches away from the claimed combinations.

a) Bazzano Fails To Teach Penetration Enhancer

Bazzano does not teach skin penetration enhancer at all, much less "to a depth of the hair bulbs."

(1) Ethanol And Propylene Glycol Is A Delivery Vehicle, Not A Penetration Enhancer

The OFFICE ACTION says ethanol and propylene glycol is not a penetration enhancer, but a "delivery vehicle." (Hoke teaches "delivery vehicles such as ethanol and propylene glycol. . . . Applicant's claims differ because they require a penetration enhancer."). OFFICE ACTION at 6 (28 Sept. 2001); accord, Bazzano at claim 24; Knowles, W.R., SUPPLEMENTAL DECLARATION at 1 (25 April 2001); Mikulak at 153 (PEG-ethanol used as inert experimental control); SPECIFICATION at pg. 17 line 15-17, pg. 18 line 16 to pg. 19 line 9; 21 C.F.R. 352.70 (Food & Drug Administration treats PEG as an inert vehicle); *see* ROGAINE® brand topical minoxidil F.D.A.-approved product insert (PEG-ethanol used as inert vehicle). [1]

(2) The Claims Exclude Bazzano's Retinoid

The OFFICE ACTION says retinoid itself is a penetration enhancer. OFFICE ACTION at 8 (28 Sept. 2001). The record is devoid of any data to indicate that it is. Applicant has, however, amended the claims to clarify that the claim term "penetration enhancer" does not include Bazzano's retinoid compounds.

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[1] Applicant has requested an AFFIDAVIT OF REFERENCES establishing that PEG-ethanol is a penetration enhancer. RESPONSE at pg. 9 (8 Feb. 2001). None has been provided. Thus, the factual assertion that ethanol-PEG is a penetration enhancer must be withdrawn. Ex parte Nouel, 158 USPQ 237 (B.P.A.I. 1967) (Relying on judicial notice for a fact invalidating a claim is reversible error); Ex parte Grochowski, No. 95-1343 at 5 (B.P.A.I. June 27, 1995); In re Ahlert, 165 USPQ 418, 420 (C.C.P.A. 1970); In re Eynde, 178 USPQ 470, 474 (C.C.P.A. 1973).

b) Bazzano Teaches Away From The Claimed Invention

Bazzano actively teaches away from the claimed invention. Bazzano says that without added retinoid, *minoxidil does not work.* Bazzano says:

> Minoxidil is recognized as being somewhat effective in producing new vellus hair growth and sparse terminal hair growth in a pre-selected group of subjects. However, its effect is far from satisfactory in most subjects. * * * minoxidil may not be able to sustain the growth of terminal hairs from the vellus hairs on the scalp. In the majority of subjects with alopecia, terminal hair growth on the scalp may not be initiated or sustained by the topical application of minoxidil nor by its systemic administration.

Id. at col. 3, line 53-56; col. 4, line 49-54. Bazzano says that without her claimed retinoid compounds, minoxidil lacks any "profound effect" and "cannot" produce a strong response. Id. at col. 5, lines 17 - 42. Bazzano explains that her claimed retinoids "can initiate cell growth and differentiation (not initiated by minoxidil)" required for hair growth. Id. Bazzano says minoxidil alone "does not appear to be a sufficient stimulus for hair growth, particularly in an area affected by alopecia." Id. at col. 4, line 63-65. Thus, Bazzano teaches away from the claimed combinations, which encompass minoxidil alone, and do not require retinoid at all.

2. Bazzano Fails To Make Obvious the Claims

Various claims stand rejected over Bazzano combined with Rajadhyaksha and Kita. The references cannot be combined, however, because (a) the *undisputed* factual teachings of the art of record teach against combining them, and (b) the combination fails to teach an express claim limitation.

a) The References Cannot be Combined

To establish a prima facie case of obviousness of the combination, the prior art must teach both (1) a sufficient motivation or suggestion to combine, and (2) a reasonable expectation of success for the combination. In re Dow Chemical Co., 5 USPQ2d 1529, 1531 (Fed.Cir. 1988) ("Both the suggestion and the expectation of success must be founded in the prior art"). Neither one is present here.

(1) The OFFICE ACTION Identifies No Suggestion To Combine In The Prior Art

Rajadhyaksha teaches a trans-dermal drug delivery patch to deliver minoxidil into the systemic blood stream. *See* Example 18; Knowles, W.R., SUPPLEMENTAL DECLARATION at ¶¶ 9

(25 April 2001). The OFFICE ACTION says it would be obvious to combine a 5*a*-reductase inhibitor with this trans-dermal drug delivery patch. The OFFICE ACTION, however, points to no suggestion in the prior art of record.

Kita discloses using vitamin D derivatives as ophthalmic agents, including ophthalmic-surgery wound healing compounds, a "dry eye" ointment, and a dermatological composition to protect the skin around the eye and scalp from ultraviolet radiation. Kita notes that vitamin D, used as sunscreen, does not create adverse effects if accidentally rubbed into the eye. Kita cannot be combined with Bazzano nor Rajadhyaksha, however, because the OFFICE ACTION identifies to no suggestion *in the prior art of record* to combine them.

Further, Kita addresses ocular surgery and ophthalmic medicine, while Bazzano addresses cosmetic hair growth. Because the references concern different technical fields, have different utilities and are pertinent to different problems, they cannot be combined. MPEP 2141.01(a) (2001).

Because the art of record has no suggestion to combine, the references cannot be combined.

(2) The References of Record Teach an Expectation of Failure - Not Success

The art of record stridently -and uniformly- suggest not combining these references. The references teach against using such systemic minoxidil or 5a-reductase inhibitor *at all* -alone or combined- for hair loss. This is due to concern over adverse side effects such as carcinogenicity, impotence and cardiac risk. Orentreich at col. 1 lines 45-51 (progesterone has systemic side effects so serious that it should not be used for hair loss; "The serious side effects (such as decreased libido) produced by the systemic administration of antiandrogens *precludes the systemic use of these drugs for the treatment of the above skin disorders.* For example, progesterone is a highly active 5*a* reductase enzyme inhibitor, but systematically disturbs the menstrual cycle in women"); Bazzano at col. 3 line 49-52; col. line 43-45 (systemic minoxidil presents serious cardiac side effect risks); Bradbury at col. 1, line 31-33 (minoxidil doesn't work well and poses significant *cardiovascular side effect risk*: "minoxidil [], a potent antihypertensive agent, as a hair growth promoting agent.... Unfortunately, not all people respond to minoxidil and the efficacy level is limited"); Hoke col. 4 lines 18-23 (progesterone's

adverse systemic effects *preclude systemic use in alopecia*), col. 3 lines 4-14 (minoxidil has "potent" cardiovascular side effects). Because of these risks, the art teaches against using penetration enhancer with either minoxidil or 5a-reductase inhibitor for hair loss.

b) The Combined References Fail To Enable The Claim Limitation "Penetration To A Depth Of The Hair Bulbs"

Rajadhyaksha teaches a 5% concentration of 5-Amino-5-ethyl-2-(3-heptyl)-1,3-dioxane ("A5A") to deliver drugs through the skin and into the systemic bloodstream. For example, Rajadhyaksha teaches various kinds of trans-dermal drug delivery skin patches. These include a trans-dermal nicotine patch (Example 28), a trans-dermal estradiol patch (Example 30), a trans-dermal birth-control progesterone patch (Example 29), and a trans-dermal minoxidil patch (Example 18). Each uses 5% A5A. Each thus delivers drug to the systemic blood stream, rather than to a "depth of hair bulbs." Knowles, W.R., SUPPLEMENTAL DECLARATION at ¶¶ 6-9 (25 April 2001). If this fact is disputed, Examiner is requested to provide an AFFIDAVIT OF REFERENCES establishing the depth of drug penetration found in Rajadhyaksha's Examples.

Because Rajadhyaksha fails to teaches penetration "to a depth of the hair bulbs," the combination cannot anticipate as a matter of law.

C. Bradbury, United States Letters Patent No. 6,124,362,

Bradbury, teaches the use of lupine triperpine compounds for hair-growth.

Claims 11 and 22 stand rejected over Bradbury. Bradbury cannot anticipate, because (1) the Applicant antedates Bradbury; (2) Bradbury requires undue experimentation to practice the claimed invention; and (3) Bradbury teaches away from the claimed combinations.

1. Applicant Antedates Bradbury

Applicant conceived of the claimed invention before Bradbury's 17 July 1998 filing date. Knowles, W.R., RULE 131 DECLARATION at ¶ 2 (9 Jan. 2002). Thus, Bradbury must be withdrawn as a reference.

2. Bradbury Requires Undue Experimentation.

In discussing his claimed lupine triterpine compounds, Bradbury mentions several thousand other, miscellaneous compounds as optional additives. This includes flavors and

sweeteners,[2] immuno-suppressants and anti-inflammatories,[3] antimicrobials,[4] thyroid hormones,[5] prostaglandin agonists and antagonists,[6] and motion sickness medicine.[7] These several thousand compounds[8] can be potentially combined to make millions and millions of potential combinations. Bradbury discloses millions of potential chemical combinations. Discerning which one of these millions of possible combinations would make the claimed inventions, would take years of research. Knowles, W.R., RULE 132 DECLARATION at ¶¶ 8-9 (15 Feb. 2001).

This is "undue experimentation." The Federal Circuit recently said that even with far fewer potential combinations, the reference must single out particular combinations:

> It is an old custom in the woods to mark trails by making blaze marks on trees. It is of no help in finding a trail or in finding one's way through the woods . . . to be confronted simply by a large number of unmarked trees. We are looking for blaze marks which single out particular trees. We see none.

Purdue Pharma L.P. v. Faulding Inc., slip op. (Fed.Cir. 25 Oct. 2000). The Federal Circuit further cautions, "the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure." Id.

Here, Bradbury has no "blaze marks" singling out or directing the skilled artisan through the millions of possible combinations, to the Applicant's specific claimed invention. Because Bradbury requires undue experimentation, it cannot anticipate. *See* Biogen, Inc. v. Amgen, Inc., 973 F.Supp. 39 (D. Mass. 1997).

3. Bradbury Teaches Away from the Claimed Invention

Bradbury actively teaches away from the claimed approach. Bradbury says hair loss preparations need lupine triterpines to be effective.

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[2] Col. 12, line 45-46; col. 22, line 29-32
[3] Col. 23, line 49; id. at line 57-67.
[4] Id. at line 50-56.
[5] Col. 24, line 1-23.
[6] Id. at line 23-29.
[7] Col. 24, line 64.
[8] Perhaps the only thing missing from this veritable cornucopia of pharmaceutical bounty is "isopropyl alcohol and propylene glycol as penetration enhancer."

Bradbury says minoxidil doesn't work well and poses significant cardiovascular side effect risk. Bradbury at col. 1, line 31-33 ("One approach for growing hair involves the much publicized use of minoxidil [], a potent antihypertensive agent, as a hair growth promoting agent.... Unfortunately, not all people respond to minoxidil and the efficacy level is limited in those individuals who do exhibit a response").

Bradbury says hair loss preparations need lupine triterpines. In so doing, Bradbury actively teaches away from the claimed invention. Knowles, W.R., RULE 132 DECLARATION at ¶¶ 8-9 (15 Feb. 2001).

D. Hoke, United States Letters Patent No. 5,994,319

Hoke teaches that the prior art compounds progesterone and minoxidil are unacceptable for hair loss (progesterone has severe adverse systemic effects, col. 4 lines 18-23; minoxidil has "potent" cardiovascular side effects and doesn't work well, col. 3 lines 4-14). Hoke instead advocates and claims the use of anti-sense nucleotides for hair loss.

Various claims stand rejected as obvious over Hoke combined with Bradbury and Rajadhyaksha. These combinations cannot anticipate the claims because (1) the Applicant has sworn behind Hoke and Bradbury, (2) the art provides no suggestion to combine (and in fact teaches to not combine) the references, (3) the combination lacks a claim limitation, and (4) the claimed invention shows secondary indicia of non-obviousness.

1. Applicant Antedates Hoke

Applicant conceived of the claimed invention before Hoke's effective date. Knowles, W.R., RULE 131 DECLARATION at ¶ 2 (9 Jan. 2002). Applicant exercised diligence from conception to both actual reduction to practice and constructive reduction to practice. Thus, Hoke must be withdrawn as a reference.

Because the Applicant antedates both Hoke and Bradbury, all rejections based on either reference **must** be withdrawn. MPEP §715.02 ¶4.

2. Hoke Teaches Away from using Minoxidil or 5a-reductase inhibitor at all, alone or combined

Hoke teaches using nucleotides. Hoke says nucleotides are safe because they are "highly selective" genetic binders. Nucleotides thus do not pose the side effect dangers of minoxidil or progesterone.

In contrast, Hoke says minoxidil doesn't work. Hoke col. 3, line 4-11 ("only 8% of patients reported a dense re-growth of scalp hair"). Thus, Hoke discourages using minoxidil *at all* - with or without penetration enhancer. Knowles, RULE 132 DECLARATION at ¶¶3-7, 14-17 (15 Feb. 2001).

3. Hoke Teaches Away From Using Penetration Enhancer At All

Hoke lacks penetration enhancer. OFFICE ACTION at 6 (28 Sept. 2001) ("Applicant's claims differ [from Hoke] because they require penetration enhancer").

Not only does Hoke lack penetration enhancer, Hoke expressly teaches away from adding it to minoxidil or 5a-reductase inhibitor. For minoxidil, Hoke says systemic use can risk cardiac arrhythmias because it is "a potent anti-hypertensive" cardiac drug. Id. at col. 5, line 4-6. Hoke thus teaches that minoxidil combined with a penetration enhancer may precipitate cardiac arrhythmias. Knowles, W.R., RULE 132 DECLARATION at ¶¶ 3-7, 14-17 (15 Feb. 2001). Thus, Hoke discourages using minoxidil with penetration enhancer. Id.

Similarly, Hoke teaches away from combining penetration enhancer with 5a-reductase inhibitor. Hoke teaches progesterone's adverse side effects like "feminization or impotency." Hoke at col. 4, line 18-24.[9] Hoke thus teaches that combining a penetration enhancer with minoxidil or progesterone is not worth the risk.

The record lacks any factual evidence to the contrary. The Examiner takes judicial notice that one would be motivated to make the combination as "the modification results in lower side effects." OFFICE ACTION pg. 7 line 8-11 (28 Sept. 2001). This factual assertion - that the combination results in *lower* side effects - is unsupported by the references of record. It is made by judicial notice only.

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[9] This danger is confirmed by the other references of record. Orentreich, for example, similarly teaches serious systemic side effects such as decreased libido and "systemic[] disrupt[ing] the menstrual cycle in women." Orentreich concludes that cardiac arrhythmias, feminization and impotency are side effects generally **not acceptable for treating hair loss**. Orentreich says these side effects **preclude systemic use** of these compounds for skin disorders. Orentreich at col. 1, line 45-52.

A suggestion to combine cannot be based solely on a judicially-noticed fact. Ex parte Grochowski, No. 95-1343 at 5 (B.P.A.I. June 27, 1995); In re Ahlert, 165 USPQ 418, 420 (C.C.P.A. 1970),. The facts concerning the state of the art may be subject to disagreement and are thus "not amenable to the taking of [judicial] notice." In re Eynde, 178 USPQ 470, 474 (C.C.P.A. 1973). If evidence regarding skill in the art (*e.g.*, a motivation to combine) is to be considered, it must be provided by a reference. Id.

Here, the uncontroverted factual evidence of record shows that Hoke teaches away from combining the references. Because of this, the rejection must be withdrawn.

4. The claimed invention shows secondary considerations of non-obviousness

The claimed invention shows many indicia of non-obviousness. The claimed combination solves a long felt need for a solution to a hairy, difficult problem. Knowles, W.R., RULE 1.132 DECLARATION (15 Feb. 2001). Dr. Knowles succeeded where others failed. Id. Dr. Knowles' results were unexpectedly superior, showing *ten times* the effectiveness of topical minoxidil, with *qualitatively better* results. Id.; SPECIFICATION at 8, lines 14-19. Thus, the invention cannot be found obvious.[10]

IV. THE DECLARATIONS

The Declarations previously accepted without objection are now considered "ineffective." Reconsideration is respectfully requested.

A. The RULE 131 DECLARATION

The OFFICE ACTION objects to the 15 Feb. 2001 RULE 1.131 DECLARATION. A replacement RULE 131 DECLARATION is accordingly enclosed. The RULE 1.131 DECLARATION establishes diligence from conception to actual reduction to practice. The RULE 1.131 DECLARATION discusses the frequency of experimental data measurement and the length of testing. Knowles, W.R., RULE 1.131 DECLARATION at ¶ 4-9 (9 Jan. 2002). The rationale for such testing is fully explained in the SPECIFICATION. *See* pg. 5 line 16-24; pg. 13 line 16 to pg.

[10] If the Examiner disagrees with these factual assertions, please provide an AFFIDAVIT OF REFERENCES establishing countermanding facts.

14 line 16. No evidence of record says this is less than diligent. To the contrary, this is perhaps the most diligent, thorough and careful research in any reference of record.[11]

B. The RULE 132 DECLARATION

The OFFICE ACTION says that the RULE 1.132 DECLARATION is ineffective because it "fails to demonstrate unexpected results." OFFICE ACTION at 10 (28 Sept. 2001). Reconsideration or provision of an AFFIDAVIT OF REFERENCES is requested.

The RULE 1.132 DECLARATION provides evidence the interpretation by one of skill in the art of the teachings of the references of record. No evidence of record contradicts this.

The RULE 1.132 DECLARATION also provides evidence of Applicant's unexpected results. These results are discussed not only in the RULE 1.132 DECLARATION, but also in the SPECIFICATION. The SPECIFICATION says, "I have found that certain compounds have greatly improved effectiveness - achieving *ten times the benefit, or an entire order of magnitude* - if combined with a skin penetration enhancer." SPECIFICATION pg. 8 line 14-19. "I have found several surprising things . . . minoxidil alone is *effective on about 8%* of patients,[12] while the same amount of minoxidil administered with the proper amount of a penetration enhancer *is effective on 35%* of patients. Testosterone blockers added to such a mix are synergistically beneficial, *increasing the efficacy from 35% to 85%* of patients." SPECIFICATION at pg. 15 line 19 to pg. 16 line 2; *see also* RULE 1.131 DECLARATION at ¶ 10 (9 Jan. 2002).

Increasing efficacy from **only 8%** to a level of **between 35-85% - with no adverse side effects** - demonstrates unexpected results; no art of record shows this level of effectiveness. If Examiner believes the 85% level of effectiveness disclosed in the SPECIFICATION and the RULE 1.132 DECLARATION would have been expected in the art, Examiner must provide an AFFIDAVIT OF REFERENCES showing prior art references teaching this expectation.

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[11] If the Examiner disagrees with these factual assertions, please provide an AFFIDAVIT OF REFERENCES establishing countermanding facts.

[12] Hoke confirms that with minoxidil, "only 8% of patients reported a dense re-growth of scalp hair." Col. 3, line 4-11.

The OFFICE ACTION appears to ask for a demonstration vis "the *same limitations* in the *closest prior art* relied upon." The prior art of record does not, however, have the same limitations as claimed invention. This is why none of the art of record is "close" at all.

V. CONCLUSION

In light of the enclosed amendments and remarks, reconsideration and prompt allowance is believed required.

Respectfully submitted,

Mark Pohl, Reg. No. 35,325
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PHARMACEUTICAL PATENT ATTORNEYS,
POHL & ASSOC. LLP
55 Madison Avenue, 4th floor (P 4014)
Morristown, NJ 07960-6397 USA

Direct: *Mark.Pohl@LicensingLaw.com*
☎ +1 (973) 665-0275

Amendments to Claims

1. A composition of matter intended for topical use in preventing or treating alopecia, or maintaining healthy hair, said composition of matter comprising:

a) an active compound selected from the group consisting of: a pharmaceutically or cosmetically effective topical amount of a ~~testosterone blocker~~ 5*a*-reductase inhibitor and minoxidil, and

b) a non-retinoid penetration enhancer, said penetration enhancer present in a concentration sufficient to aid said active compound in penetrating the skin surface to a depth of approximately the depth of hair bulbs.

2. The composition of claim 1, wherein said active compound comprises a 5*a*-reductase inhibitor~~testosterone blocker~~.

3. The composition of claim 1, wherein said active compound comprises minoxidil.

4. The composition of claim 3, further comprising a 5*a*-reductase inhibitor~~testosterone blocker~~.

5. The composition of claim 4, wherein the ratio of ~~penetration enhancer to~~ 5*a*-reductase inhibitor ~~testosterone blocker~~ to minoxidil in the composition is approximately ~~5 drops : 0.5~~ grams : 1 gram.

~~6. The composition of claim 4, wherein said penetration enhancer is trimethyl acetate and wherein said testosterone blocker is progesterone.~~

7. The composition of claim 5, wherein said 5*a*-reductase inhibitor ~~testosterone blocker~~ is present in a concentration of 0.5 grams per 4 ounces of finished liquid. ≒ 0.4 %

8. An article of manufacture comprising ~~T~~the composition of claim 4, labeled for topical cosmetic use in maintaining normal, healthy hair.

9. An article of manufacture comprising t~~T~~he composition of claim 4, labeled for topical pharmaceutical use in preventing or treating a disease.

10. The article of manufacture ~~composition~~ of claim 9, wherein said disease comprises alopecia.

11. The composition of claim 4, further comprising a sunscreen in an amount effective to screen radiation.

12. A method for preventing or treating alopecia, or maintaining healthy hair, said method comprising:

a) Topically administering an active compound selected from the group consisting of: a pharmaceutically or cosmetically effective topical amount of a ~~testosterone blocker~~ 5α-reductase inhibitor and minoxidil, together with

b) a non-retinoid penetration enhancer, said penetration enhancer present in a concentration sufficient to aid said active compound in penetrating the skin surface to a depth of approximately the depth of hair bulbs.

13. The method of claim 12, wherein said active compound comprises a 5α-reductase inhibitor~~testosterone blocker~~.

14. The method of claim 12, wherein said active compound comprises minoxidil.

15. The method of claim 14, wherein said active compound further comprises a 5α-reductase inhibitor~~testosterone blocker~~.

16. The method of claim 15, wherein the ratio of ~~penetration enhancer to~~ 5α-reductase inhibitor ~~testosterone blocker~~ to minoxidil in the composition is approximately ~~5 drops :~~ 0.5 grams : 1 gram.

~~17. The method of claim 15, wherein said penetration enhancer is trimethyl acetate and wherein said testosterone blocker is progesterone.~~

18. The method of claim 16, wherein said 5α-reductase inhibitor ~~testosterone blocker~~ is present in a concentration of 0.5 grams per 4 ounces of finished liquid.

19. The method of claim 15, labeled for topical cosmetic use in maintaining normal, healthy hair.

20. The method of claim 15, labeled for topical pharmaceutical use in preventing or treating a disease.

21. The method of claim 20, wherein said disease comprises alopecia.

22. The method of claim 15, further comprising a sunscreen in an amount effective to screen radiation.